

### **Remarks**

Before entry of the present Amendment, claims 1-16, 18-49 and 54-83 were pending in the present application. Claims 8-9, 12-14, 21, 22, 30-49 and 56-83 have been withdrawn from consideration by the Examiner. Thus, claims 1-7, 10, 11, 15, 16, 18-20, 23-29, 54 and 55 are currently pending and stand rejected.

With this response, claim 1 has been amended to recite that the water insoluble nanoparticle comprises “a biocompatible outer layer which is adsorbed onto said neutron capture element,” and support can be found in the specification, for example, on page 16, lines 29-30. Claim 2 has been canceled. Claims 3-14, 18, 23, 25, 28, 31, 36, 49 have been rewritten in proper dependent format. Claims 4-7, 10, 11, 15, 16, 18-20, 23-29, 54 and 55 have been amended to recite “water insoluble nanoparticle(s),” and withdrawn claims 8-9, 12-14, 21, 22, 36, 37, 46, 49, 56-62 and 72-83 also have been amended for consistency. Claim 3 has been amended to recite “biocompatible outer layer” as requested by the Examiner.

No new claim has been added. No new matter has been added by the present Amendment. Applicant specifically reserves the right to pursue the subject matter of the canceled or amended claims in a related application. Applicant respectfully requests reexamination and reconsideration of the case in light of the present Amendments and the following remarks. Each of the rejections levied in the Office Action is addressed individually below.

### **Species Election**

Claim 10 has been withdrawn by the Examiner from further consideration as being drawn to non-elected subject matter. Applicant traverses the withdrawal of claim 10. Applicant respectfully submits that claim 10 reads on the elected species of Boron-containing glass or glass ceramic as the neutron capture element form.

Claim 10 depends from claim 1 or 3, and recites that said neutron capture element is in particulate form. Boron-containing glass or glass ceramic may be in particulate form, as implied by the description on page 15, line 34 to page 16, line 4 in the present application. Applicant thus submits that claim 10 reads on the elected species.

Applicant respectfully requests that the Examiner rejoin claim 10, which was withdrawn from examination in error.

### Objection to the Specification

The Examiner has objected to the specification and has requested correction on the referencing to and brief description of the drawing for Figure 1. Applicant has amended the paragraph beginning on page 15, line 16 to refer to Figure 1a. Thus, this objection is rendered moot by the present Amendment.

### Objection to the Claims

The Examiner has objected to the claims and has requested correction of informalities for consistency. Applicant has amended claims 4-7, 10, 11, 15, 16, 18-20, 23-29, 54 and 55 to recite “water insoluble nanoparticle(s)” and claim 3 to recite “biocompatible outer layer,” thereby rendering the objection moot.

### Rejection under 35 U.S.C. § 102(b) for alleged lack of novelty

Claims 1-7, 18, 20, 25-28 and 54 stand rejected under 35 U.S.C. § 102(b) on the ground that they are anticipated by Ferrari (U.S. Patent 6,107,102). The Examiner has stated that Ferrari discloses a microstructural device or suspension of microdevices that anticipates the claimed subject matter.

Applicant respectfully submits that Ferrari does *not* disclose any nanoparticles as defined within the present claims. As amended, claim 1 incorporates the feature of now-canceled claim 2 and recites “a biocompatible outer layer which is adsorbed onto said neutron capture element.” In contrast, as the Examiner has acknowledged, Ferrari discloses that “[t]he microstructural device may have two or more layers, such as an outer hydrophilic polymer coating, such as PVP, PEG, etc. (column 2, lines 49-60; column 12, lines 9-17) which is covalently linked to the microdevice (column 5, lines 34-52).” *See*, Office Action dated May 22, 2009, on page 4, lines 3-6. Ferrari, at best, teaches chemically attaching a polymeric outer layer to a lipid layer, which in turn is anchored on surface of microstructures. There is no teaching or suggestion in Ferrari that the biocompatible outer layer is *adsorbed* onto the neutron capture element as recited in claim 1. Therefore, claim 1 and the dependent claims 3-7, 18, 20, 25-28 and 54 can not be anticipated by Ferrari, and Applicant respectfully requests that the rejection be removed.

Claims 1, 4, and 11 stand rejected under 35 U.S.C. § 102(b) on the ground that they are anticipated by Loyalka *et al.* (WO 00/45826).

As amended, the claims recite the feature of now-canceled claim 2, which has not been rejected as anticipated by Loyalka. As a result, the rejections by Loyalka under 35 U.S.C. § 102(b) should be withdrawn.

Rejection under 35 U.S.C. § 103(a) as allegedly being obvious

Claims 1-7, 15, 16, 18-20, 23-29, 54 and 55 stand rejected under 35 U.S.C. § 103(a) on the ground that they are unpatentable over Ferrari (U.S. Patent 6,107,102). The Examiner has stated that it would have been obvious to one with ordinary skill in the art to reach the claimed subject matter by combining Ferrari with the art in the area or routine experimentation. Applicant respectfully disagrees.

As established above, the claims have been amended to recite that the water insoluble nanoparticle comprises “a biocompatible outer layer which is adsorbed onto said neutron capture element.” Nowhere in Ferrari is there any mention of an adsorbed biocompatible outer layer on the neutron capture element as recited in claims. Nor has the Examiner pointed to any art that can cure the deficiency of Ferrari, even assuming a proper combination could have been made. Furthermore, the present specification demonstrates surprising and unexpected features of water insoluble nanoparticles with a biocompatible outer layer adsorbed on an inorganic neutron capture element as recited in the present claims. For example, the present specification demonstrates that such water insoluble nanoparticles with an adsorbed biocompatible outer layer target to tumor sites, resulting in a preferential accumulation of these nanoparticles in tumor tissue compared to normal tissue (page 34, lines 1-15 of the present application). There is no teaching or suggestion in Ferrari, even if combined with art in the area or routine experimentation of either the structure or the properties of the nanoparticles recited in the present claims. Applicant, therefore, respectfully requests that the rejection be removed.

### Conclusion

For all of the reasons set forth above, each of the rejections in this case should be removed and the application should proceed to allowance. A Notice to that effect is respectfully requested.

If, at any time, it appears that a phone discussion would be helpful, the undersigned would greatly appreciate the opportunity to discuss such issues at the Examiner's convenience. The undersigned can be contacted at (617) 248-5175.

Please charge any fees that are *necessary* to maintain pendency and/or protect the filing date of the present application to our Deposit Account Number 03-1721, referencing our Docket Number 2003882-0016.

Respectfully submitted,

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Date: August 24, 2009